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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,627	09/14/2001	Luigi Naldini	131.14-US-WO	5935

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GATES & COOPER LLP
HOWARD HUGHES CENTER
6701 CENTER DRIVE WEST, SUITE 1050
LOS ANGELES, CA 90045

EXAMINER

ZEMAN, ROBERT A

ART UNIT PAPER NUMBER

1645

DATE MAILED: 10/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/831,627

Applicant(s)

NALDINI ET AL.

Examiner

Robert A. Zeman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7-13-05 has been entered.

The amendment and response filed on 7-13-2005 are acknowledged. Claims 1 and 2 have been amended. Claims 1-8 are pending. Claim 8 remains withdrawn from consideration. Claims 1-7 are currently under examination.

With regard to Applicant's traversal of the Restriction Requirement, the requirement was made final in the Office action on 3-2-2005 and hence will not be revisited here. Applicant reminded he is free to petition the Director with regard to this matter.

Claim Rejections Withdrawn

The rejection of claims 1-7 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-16 of U.S. Patent No. 5,994,136 is withdrawn in light of the amendment to claim 1.

The rejection of claims 1-7 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-9 of U.S. Patent No. 6,428,953 is withdrawn in light of the amendment to claim 1.

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The rejection of claims 1-3 and 5-6 under 35 U.S.C. 102(b) as being anticipated by Sadaie et al. (Virology, 1992, Vol. 187, pages 604-611) is withdrawn in light of the amendment to claim 1.

The rejection of claims 1-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Naldini et al. (U.S. Patent No. 5,994,136) is withdrawn in light of the amendment to claim 1. The rejection of claim 2 under 35 U.S.C. 112, second paragraph, as being vague and indefinite by the use of the term "carried by a virus particle" is withdrawn in light of the amendment thereto.

Claim Rejections Maintained

35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1-5 and 7 under 35 U.S.C. 102(b) as being anticipated by Ory et al. (PNAS, 1996, Vol. 93, pages 11400-11406 – IDS-8) for reasons of record.

The instant claims are drawn to methods of amplifying (propagating) an envelope defective retrovirus by contacting said retrovirus to a cell that comprises a gene that encodes a virus envelope integrated into its genome wherein said envelope gene complements said

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retrovirus. The instant claims have been amended to recite the limitation that said envelope gene is integrated into the cell's genome. Newly added claims recite the limitations: that the envelope protein is VSVG (claim 4); that the retrovirus comprises an immunodeficiency virus; and that the envelope gene is controlled by an inducible promoter. Moreover, while the instant claims require that the envelope gene be integrated, there is no requirement as to when said integration occurs. Consequently the instant claims only require that the envelope defective virus is amplified (claim 1), that the propagated virus comprises the envelope encoded by the integrated gene within the cell and that said envelope is expressed by said cell.

Applicant argues the amendments to the instant claims renders the aforementioned rejection moot. Applicant's arguments have been fully considered and deemed non-persuasive.

Ory et al. disclose the sequential exposure of 293 cells to first a retroviral vector (MuMLV-Env defective) and then subsequently to a plasmid encoding VSV-G envelope protein (see Figure 2).

As outlined previously, Ory et al. disclose a packaging cell line for the production of high titer retroviruses with VSV G protein (envelope protein) [see abstract]. Ory et al. further disclose the transfecting of cells with a retroviral vector (MuMLV-Env defective) and a plasmid encoding VSV-G envelope protein (see page 11401, 1st column and page 11403). Ory et al. further disclose the use of an inducible promoter to regulate the expression of the VSVG envelope protein (see page 11402, 1st column). Ory et al. also disclose that said cells expressed VSV-G on its surface (see page 11401, 2nd column and page 11403). The resulting "psuedotypes" (i.e. viruses produced by the transfected cells) contain VSV-G envelope proteins on their surface (see

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pages 11405-11406). Consequently, Ory et al. anticipates all the limitations of the rejected claims.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is rendered vague and indefinite by the use of the term “incorporate”. It is unclear what is meant by said term since it is not explicitly defined in the specification. The term “incorporate” suggests that said envelope protein is internalized. Therefore, it is unclear whether said limitation meant to include anything other than the recited envelope protein to serve as the viral envelope for the virus particles produced by said indicator cell line? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim Rejections - 35 USC § 102

Claims 1-3 and 5-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Gruber et al. (U.S. Patent 5,503,974).

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Gruber et al. disclose a method of amplifying replication deficient retroviruses by bringing said replication deficient retroviruses (which can lack *env*) in contact with cells that have the *env* gene within their genome (see column 6, lines 50-57).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gruber et al. (U.S. Patent 5,503,974) and Ory et al. (PNAS, 1996, Vol. 93, pages 11400-11406 – IDS-8)

The instant claims are drawn to methods of amplifying (propagating) an envelope defective retrovirus by contacting said retrovirus to a cell that comprises a gene that encodes a virus envelope integrated into its genome wherein said envelope gene complements said

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retrovirus. The instant claims have been amended to recite the limitation that said envelope gene is integrated into the cell's genome. Newly added claims recite the limitations: that the envelope protein is VSVG (claim 4); that the retrovirus comprises an immunodeficiency virus; and that the envelope gene is controlled by an inducible promoter. Moreover, while the instant claims require that the envelope gene be integrated, there is no requirement as to when said integration occurs. Consequently the instant claims only require that the envelope defective virus is amplified (claim 1), that the propagated virus comprises the envelope encoded by the integrated gene within the cell and that said envelope is expressed by said cell.

Gruber et al. disclose a method of amplifying replication deficient retroviruses by bringing said replication deficient retroviruses (which can lack *env*) in contact with cells that have the *env* gene within their genome (see column 6, lines 50-57).

Gruber et al. differs from the instant invention in that they don't disclose the use of GVSG as the viral envelope gene (*env*).

Ory et al. disclose a packaging cell line for the production of high titer retroviruses with VSV G protein (envelope protein) [see abstract]. Ory et al. further disclose the transfecting of cells with a retroviral vector (MuMLV-Env defective) and a plasmid encoding VSV-G envelope protein (see page 11401, 1st column and page 11403). Ory et al. further disclose the use of an inducible promoter to regulate the expression of the VSVG envelope protein (see page 11402, 1st column). Ory et al. also disclose that said cells expressed VSV-G on its surface (see page 11401, 2nd column and page 11403). The resulting "psuedotypes" (i.e. viruses produced by the transfected cells) contain VSV-G envelope proteins on their surface (see pages 11405-11406).

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It would have been obvious for one of skill in the art to use the VSV G envelope protein/gene disclosed by Ory et al. in the method disclosed by Gruber et al. in order to take advantage of broader tropism associated with VSVG.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

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Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



ROBERT A. ZEMAN
PATENT EXAMINER

September 30, 2005